DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#27

APR - 9 1997

Re: CEDAX (CAPSULE 1)®
Docket No. 96E-0102

Stephen G. Kunin
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, D.C. 20231

Dear Mr. Kunin:

This is in regard to the patent term extension application for U.S. Patent No. 4,634,697 filed by Schering-Plough Corporation under 35 U.S.C. § 156. The patent claims the human drug product CEDAX (CAPSULE 1)® (ceftibuten dihydrate), New Drug Application (NDA) 50-685.

In the September 3, 1996 issue of the Federal Register (61 Fed. Reg. 46465), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before March 3, 1997, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely,

Glen Drew

for Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Thomas D. Hoffman
Schering-Plough Corporation
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